

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**AUXILIUM PHARMACEUTICALS,
INC. & FCB I LLC,**

Plaintiffs,

v.

WATSON LABORATORIES, INC.,

Defendant.

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Civil Action No. 12-3084 (JLL)

OPINION

I. INTRODUCTION

This matter comes before the Court by way of defendant Watson Laboratories, Inc.’s (“Watson”) motion for leave to amend its answer to add a counterclaim for inequitable conduct (ECF No. 80-1). Plaintiffs Auxilium Pharmaceuticals, Inc. and FCB I LLC (collectively “Auxilium”) oppose Watson’s request (ECF No. 83).

Auxilium has brought an action for patent infringement against Watson pursuant to 35 U.S.C. § 271. Watson claims that during the early stages of fact discovery, Auxilium produced confidential documents that led to the discovery of new facts suggesting the patents-in-suit are unenforceable due to inequitable conduct. Def. Br., ECF No. 80-1 at 1. Auxilium claims any such amendments are futile. Pl. Opp’n Br., ECF No. 83 at 1. For the reasons set forth below, the Court will grant Watson’s motion to amend.

I. BACKGROUND

A. Factual History

For purposes of the motion to amend, the Court must accept as true all well-pleaded allegations in the proposed amended answer. See Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009). Therefore, the Court recites the facts relevant to Watson’s motion, as alleged in Watson’s proposed answer, but makes no factual findings. The patents-in-suit list one inventor, Robert J. Gyurik. Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶ 5. Watson alleges Gyurik misrepresented to the United States Patent and Trademark Office (“PTO”) that he was the sole inventor. Id. ¶¶ 9-60. The PCT ’235 application was filed on April 21, 2003. Id. ¶ 9. Watson alleges that before Gyurik filed any application, Conrex Pharmaceuticals Corporation (“Conrex”) had developed and tested a pharmaceutical composition comprising of testosterone (an androgen), a Hsieh enhancer (CPE-215), and a carbomer (a thickening agent). Id. ¶ 18. Further, Watson alleges Conrex had developed and tested certain testosterone formulations, recorded the results, and submitted the information to Bentley Pharmaceuticals, Inc. (“Bentley”), Gyurik’s employer at the time he filed the ’724 Application and PCT ’235 Application. Id. Watson alleges that Gyurik, as a Bentley employee, had access to Conrex’s Formulation Assets, which were purchased by Bentley in 1999, prior to the filing of the ’724 Application and PCT ’235 Application and knew that Conrex had developed and tested compositions containing an androgen, a Hsieh enhancer, and a thickening agent. Id. ¶¶ 25-26. Further, Watson alleges Gyurik used CPE-215 in his studies and relied on it as the basis for the invention, essentially claiming it as his own. Id. ¶ 28. Based on these allegations, Watson argues that Conrex should have been named as a co-inventor. Id. ¶ 29.

B. Procedural History

Auxilium filed a complaint against Watson for infringement of the patents-in-suit. Compl., ECF No. 1. Auxilium's Complaint contends that Watson's Abbreviated New Drug Application ("ANDA") to the FDA and its Paragraph IV certifications directed to each of the patents-in-suit constitute patent infringement under 35 U.S.C. § 271(e)(2)(A). Id. On April 18, 2013, the final day to amend pleadings pursuant to the Court's initial scheduling order (ECF No. 36), Watson filed a motion for leave to amend its answer and counterclaims to add defenses and counterclaims related to inequitable conduct. Mot. to Am., ECF No. 69. The Court entered an Order granting Watson's request and setting a May 10, 2013, deadline for Watson to re-file its motion. Order, ECF No. 71. Watson now seeks to amend its Answer to include a counterclaim for inequitable conduct, arguing it learned, through discovery, that each of the patents-in-suit was obtained through inequitable conduct before the PTO. Def. Br., ECF No. 80-1 at 4-5.

III. DISCUSSION

A. Standard - Motion to Amend

Under Rule 15, the decision to permit an amendment rests in the sound discretion of the Court. See Heyl & Paterson Int'l Inc. v. F.D. Rich Hous. of V.I., Inc., 663 F.2d 419, 425 (3d Cir. 1981) (citing Forman v. Davis, 371 U.S. 178, 182 (1962)). The Supreme Court has stated that leave to amend under Rule 15 may be denied in case of: (1) undue delay; (2) bad faith or dilatory motive; (3) undue prejudice; or (4) futility of amendment. See Foman, 371 U.S. at 182; see also Arthur v. Maersk, Inc., 434 F.3d 196, 204 (3d Cir. 2006). Stated differently, "absent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless denial can be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by

amendments previously allowed[,] or futility of amendment.” Long v. Wilson, 393 F.3d 390, 400 (3d Cir. 2004) (citations, internal quotation marks, and emphasis omitted).

Here, Watson objects to the Amended Answer on the grounds of futility. Pl. Opp’n Br., ECF No. 83. Watson does not, however, argue that the Court should deny leave to amend on the basis of bad faith by Auxilium, prejudice to Watson, or undue delay to the Court. See id. Upon its own review of the record, the Court does not independently find reason to deny leave for Auxilium to amend on the basis of bad faith, prejudice to Watson, or undue delay. Thus, the Court will discuss only whether the proposed amendments are futile.

A court will consider an amendment futile if it “is frivolous or advances a claim or defense that is legally insufficient on its face[.]” Harrison Beverage Co. v. Dribeck Imps., Inc., 133 F.R.D. 463, 468 (D.N.J. 1990) (internal citations and quotations marks omitted). In determining whether an amendment is “insufficient on its face,” the Court employs the same standard it applies to a Rule 12(b)(6) motion to dismiss. See In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997). Detailed factual allegations are not necessary to survive a Rule 12(b)(6) motion, but the pleader must supply “more than labels and conclusions[.]” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 545 (2007).

A two-part analysis determines whether this standard is met. Fowler, 578 F.3d at 210 (interpreting Ashcroft v. Iqbal, 556 U.S. 662 (2009)). First, a court separates a claim’s factual and legal elements. Id. All well-pleaded facts set forth in the pleading and the documents incorporated therein must be accepted as true, but a court may disregard any legal conclusions. Id.; Iqbal, 556 U.S. at 678. Second, a court must determine whether the pleader articulates “enough facts to state

a claim to relief that is plausible on its face.” Twombly, 550 U.S. at 570; accord Fowler, 578 F.3d at 211.

B. Inequitable Conduct

Patent applicants “have a duty to prosecute patent applications in the Patent Office with candor, good faith, and honesty.” Marlowe Patent Holdings LLC v. Dice Elecs., No. 10-1199, 2013 U.S. Dist. LEXIS 26533, at *17 (D.N.J. Feb. 27, 2013) (quoting AstraZeneca Pharms. LP v. Teva Pharms. USA, 567 F. Supp. 2d 683, 691 (D.N.J. 2008)). “A breach of this duty constitutes inequitable conduct and renders the entire patent unenforceable[.]” Id. Both parties cite to Exergen Corp. for the standard of inequitable conduct. See Def. Br., ECF No. 80-1 at 6; Pl. Opp’n Br., ECF No. 83 at 8; see also Def. Reply Br., ECF No. 87 at 2-4. The Federal Circuit in Exergen Corp. held the substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive. See Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009) (denying movant’s motion to amend its pleading because the pleading did not provide any factual basis to infer that any specific individual, who owed a duty of disclose in prosecuting the patent at issue, knew of the specific information that allegedly should have been disclosed).

Inequitable conduct is considered a broader concept than fraud. Nonetheless, inequitable conduct must be pled with particularity. See Southco, Inc. v. Penn Eng’g & Mfg. Corp., 768 F. Supp. 2d 715, 720 (D.Del. 2011). To plead inequitable conduct with particularity “the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or

omission committed before the PTO” and “allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.” Exergen Corp., 575 F.3d at 1327-28; Waddington N. Am., Inc. v. Sabert Corp., No. 09-4883, 2010 U.S. Dist. LEXIS 103955, at *14 (D.N.J. Sept. 29, 2010). The requisite state of mind for inequitable conduct includes: (1) knowledge of the withheld material information or of the falsity of the material misrepresentation; and (2) specific intent to deceive the PTO. Exergen Corp., 575 F.3d at 1327; Taro Pharm. N. Am. Inc. v. Suven Life Scis., LTD., No. 11-2452, 2012 U.S. Dist. LEXIS 89702, at *14 (D.N.J. June 28, 2012).

1. But-For Materiality

The Federal Circuit has held the materiality required to establish inequitable conduct is “but-for materiality.” Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291 (Fed. Cir. 2011).¹ In other words, information is material when “but-for” the alleged omission, the examiner would not have issued the patent. See XpertUniverse, Inc. v. Cisco Sys., Inc., 868 F. Supp. 2d 376, 382 (D.Del. 2012); Therasense, 649 F.3d at 1291.

Watson claims that but for the non-disclosure of the withheld Conrex information and but for Gyurik’s misrepresentation, the claims of the patents-in-suit would not have issued.² See Def.

¹ There is an exception in “cases of affirmative egregious misconduct.” Therasense, Inc., 649 F.3d at 1292 (Fed. Cir. 2011); see also Taro Pharm. N. Am. Inc., 2012 U.S. Dist. LEXIS 89702, at *19. “Such cases do not require a showing of materiality because where a party engaged in a ‘deliberately planned and carefully executed scheme,’ materiality is assumed.” Taro Pharm., 2012 U.S. Dist. LEXIS 89702, at *19 (citing Therasense, 649 F.3d at 1291-92). However, the Court need not address this exception because it finds Watson has satisfied but-for materiality.

² In the alternative, Watson argues that Conrex’s research is material to the prosecution of the patents-in-suit because the “information, formulations, and assets sold constitute prior art
(continued...)

Reply Br., ECF No. 87 at 8-9; see also Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶¶ 17, 31, 33-34, 37-38, 40, 45-46, 51-52, 56. Watson alleges that Gyurik was not the “original, first, and sole inventor” of the inventions claimed in the ’724 Application, the PCT ’235 Application, the ’968 patent, or the inventions claimed in any of the patents-in-suit. Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶ 33. According to Watson, Conrex, prior to Gyurik’s involvement, developed and tested testosterone gel formulations containing an androgen (testosterone), a Hsieh enhancer, and a thickening agent, which Watson alleges is almost identical to what is claimed in the patents-in-suit. Def. Reply Br., ECF No. 87 at 9. Further, Watson alleges that Gyurik knew of Conrex’s testosterone formulations and derived the pharmaceutical formulations claimed in of all of the patents-in-suit from the testosterone formulations developed and tested by Conrex. Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶¶ 36-37. Therefore, Watson alleges that Gyurik falsely claimed as his own invention the subject matter in the patent applications to which all of the patents-in-suit claim priority. Id. ¶ 29. Moreover, Watson claims that at no time during the prosecution of the ’724 application or during the prosecution of any of the patents-in-suit did Auxilium correct or inform the PTO that Gyurik had knowledge of and had referenced Conrex’s testosterone formulations when developing the purported inventions. Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶ 36.

²(...continued)
under 35 U.S.C. § 102(b) that renders the claims of all the Patents-in-Suit invalid as obvious under 35 U.S.C. § 103.” Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶ 64. Furthermore, Watson argues that the research is “material to the prosecution . . . because it was transmitted to the named inventor on the Patents-in-Suit and therefore qualifies as prior art under 35 U.S.C. § 102(f) that renders the claims of all the Patents-in-Suit invalid as obvious under 35 U.S.C. § 103.” Id. Watson alleges that during the prosecution, Auxilium did not inform the PTO that Conrex had sold its research to Yuntai HSU, who then in turn sold the research to Bentley (Gyurik’s employer), more than one year prior to the filing of the earliest patent application to which the patents-in-suit claim priority. Id. ¶ 63.

In its opposition, Auxilium contends that Watson’s motion to amend is futile because it does not satisfy the high pleading standards of inequitable conduct as set forth by Exergen Corp. Pl. Opp’n, ECF No. 83 at 10. Auxilium alleges that Watson does not identify “a single, issued claim of the patents-in-suit with respect to its inequitable conduct allegations” and that Watson’s proposed Amended Answer identifies only certain preliminary, composition claims that were either cancelled during prosecution, or were subsequently amended to include additional limitations. *Id.* at 14, 16.

In the alternative, Auxilium argues that even if Watson had directed its inequitable conduct allegations to the claims of the patents-in-suit, the proposed inequitable conduct claim is still futile because Watson does not show that any of the prior art references would have been “but for material.” *Id.* at 16. Auxilium alleges that the Asset Purchase Agreement “is more notable for what it does not disclose.”³ *Id.* at 17. Auxilium contends that the “significant differences in scope” between the Asset Purchase Agreement and the specific testosterone formulation of the patents-in-suit demonstrate that the agreement is not “‘but for material’ to patentability and would not have caused the PTO to not issue the claims of the patents-in-suit.” *Id.* Auxilium also alleges that Watson’s reliance on the Conrex in vitro research fails because the purpose of the Conrex in vitro research was to establish a patch product, not a testosterone gel. *Id.* at 18. Auxilium contends that Watson’s allegations about Mr. Gyurik’s laboratory notebooks are false and that the Conrex formulations “did not work and resulted in a ‘[b]ig glob.’” *Id.* at 19.

The Court finds that Watson’s allegations regarding inequitable conduct satisfy “but-for materiality.” Watson’s proposed amendment includes allegations detailing why the withheld

³ Auxilium alleges that the Asset Purchase Agreement does not disclose a topical testosterone gel or a method of maintaining effective testosterone levels in a male with hypogonadism “by transdermally delivering the composition including testosterone and the enhancer recited in the asserted claims.” Pl. Opp’n, ECF No. 83, at 17.

information and prior art identified are material. See Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶¶ 61-63, 73. According to Watson, the omission of these results could have led the examiner not to issue the patent because “[h]ad the USPTO known that Gyurik was not the first to invent a pharmaceutical composition or method of using . . . an androgen, a Hsieh enhancer, and a gelling agent, the USPTO would not have granted . . . any of the [p]atents-in-[s]uit[.]” Id. ¶ 37. Watson has alleged sufficient facts supporting its claim that “but-for” these details, the PTO would not have issued the patent. See *Therasense*, 649 F.3d at 1295-96 (remanding the case to the District Court to determine whether the PTO would not have granted the patent “but-for” plaintiff’s failure to disclose); *Taro Pharm. N. Am. Inc.*, 2012 U.S. Dist. LEXIS 89702, at *17 (finding that but-for materiality is lacking when an examiner has all relevant materials before him, expressly considered the materials, and still grants the patent). Furthermore, false claims to inventorship are highly material to patentability. See *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 830 (Fed. Cir. 2010) (“[The] district court did not clearly err in finding that [the alleged inventor] withheld highly material information when he ‘concealed the most critical information: he was not the inventor he claimed to be.’”); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000) (“As a critical requirement for obtaining a patent, inventorship is material.”). Therefore, the Court finds that Watson’s allegations regarding inequitable conduct satisfy but-for materiality because the omission of the co-inventor could have led the examiner not to issue the patent.

The amendments proposed by Watson also allege that Auxilium allegedly breached its duty of candor, good faith, and honesty to the PTO. See *Marlowe Patent Holdings LLC*, 2013 U.S. Dist. LEXIS 26533, at *17; *Taro Pharm. N. Am. Inc.*, 2012 U.S. Dist. LEXIS 89702, at *11-12. As

alleged in Watson's proposed Amended Answer, Gyurik misrepresented that he was the "sole inventor" to which "all of the patents-in-suit claim priority." See Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶¶ 17, 27, 28. Such conduct, if true, could establish Gyurik breached his duty.

Many of Auxilium's arguments in its opposition relate to the merits of Watson's claims. Such arguments, however, are unavailing at the pleading stage. Auxilium stresses that Watson's proposed inequitable conduct pleading is futile because it "failed to plead with specificity (because it cannot) that the Asset Purchase Agreement ("APA") or Conrex *in vitro* research are 'but-for' to the patentability of the claimed inventions, as required by [Exergen Corp.]." Pl. Opp'n, ECF No. 83 at 16-17. Auxilium argues the APA does not disclose a topical testosterone gel at all and that "[t]he significant differences in scope between the general disclosure of the [APA] and the specific testosterone formulation . . . make clear that this agreement is far from being 'but for material' to patentability and would not have caused the PTO not to issue the claims of the patents-in-suit." Id. at 17. However, at the pleading stage, the Court must accept all of Watson's factual allegations, and any reasonable inferences that can be drawn from them, as true. See *Ashcroft*, 556 U.S. at 678; Marlowe Patent Holdings LLC, 2013 U.S. Dist. LEXIS 26533, at *16; *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. 11-54, 2013 U.S. Dist. LEXIS 37582, at *51 (D.Del. Mar. 19, 2013); Eisai Co., LTD. v. Teva Pharms. USA, Inc., 247 F.R.D. 445, 450 (D.N.J. 2007) (stating that defendant is under no duty to offer evidence, prove its case or surpass a clear and convincing evidence standard); see also Great W. Mining & Mineral Co. v. Fox Rothschild LLP, 615 F.3d 159, 175 (3rd Cir. 2010) (stating that all pleaded allegations must be viewed in the light most favorable to the moving party). Therefore, accepting all of Watson's alleged facts as true, the Court finds that Watson's inequitable conduct allegations are "but-for material" because the omissions could have led a reasonable

Examiner not to issue the patents-in-suit. Although the Court takes no position on the merits of Watson's allegations, or whether Watson ultimately will be able to prove the allegations, the Court concludes that the proposed amendments sufficiently plead the "but-for materiality" standard required to maintain the counterclaim for inequitable conduct.

2. Intent to Deceive

Watson alleges: (1) that during the prosecution of the patents-in-suit, "Gyurik knew of Conrex's research concerning pharmaceutical compositions comprising testosterone and oxacyclohexadecan-2-one, and specifically the July 1994 Testosterone Permeation Study, and the September 1994 Testosterone Permeation Study"; (2) Gyurik knew the information came from Conrex through Bentley's purchase of Conrex's research and knew that the information was material to the patentability of the patents-in-suit; (3) during the prosecution, the applicants withheld information about Conrex's prior research and the sale and transmission of that research from the PTO; and (4) Gyurik used the Conrex formulations in his research and actually derived the claimed formulations from the testosterone formulations developed and tested by Conrex. Prop. Am. Answer, Affirmative Defenses, ECF No. ¶¶ 68-69, 73. Therefore, Watson concludes the single most reasonable inference is that Gyurik intended to deceive the PTO in order to obtain the patent by "falsely misrepresent[ing] to the PTO that he was the [sole] inventor of the subject matter of the patents-in-suit[.]" See *id.* ¶ 74; Def. Reply Br., ECF No. 87 at 10. In support of its position, Watson cites to *Jordan Acquisition Group*, in which the district court upheld an inequitable conduct pleading, finding an intent to deceive when the applicant failed to name co-inventors. See *Jordan Acquisition Grp., L.L.C. v. TSI Inc.*, No. 10-11988, 2011 U.S. Dist. LEXIS 72317 (E.D. Mich. July 6, 2011).

In addition, Watson contends Auxilium's arguments are attempts to offer facts and evidence on the full merits of inequitable conduct, which is not appropriate at the pleading stage. Def. Reply Br., ECF No. 87 at 11.

In opposition, Auxilium contends Watson's pleading fails to meet the Exergen standard for "intent to deceive" because Watson does not set forth sufficient allegations of underlying facts from which the Court may reasonably infer that Gyurik "withheld or misrepresented this information with a specific intent to deceive the PTO." Pl. Opp'n, ECF No. 83 at 20. Instead, Watson "makes only general allegations" that Gyurik intended to deceive the PTO by submitting "false inventorship" and by "withholding the information about Conrex's prior research, and the sale and transmission of that research to Bentley and Gyurik, in order to obtain allowance of the Patents-in-Suit." See id; see also Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶¶ 53, 58, 74. Auxilium argues Watson's allegations are "belied by other statements in its Proposed Amended Answer that are directed to the Asset Purchase Agreement that resulted in the sale of certain assets, including certain patents and technology, from Conrex to Bentley via Mr. Hsu." Pl. Opp'n, ECF No. 83 at 20-21. Auxilium posits that Watson's allegations make clear that Bentley, not Gyurik, owned the Conrex research at the time Gyurik began his research in April 2000, as well as when Gyurik signed the inventorship declaration in September 2003. Id. at 21. Auxilium also argues that because Bentley owned the results of Gyurik's inventive work, neither Gyurik nor Bentley had anything to gain (financial or otherwise) from withholding the Conrex in vitro research from the PTO. Id. (referencing Schering Corp. v. Mylan Pharms., Inc., No. 09-6383, 2012 WL 1473329, at *7 (D.N.J. Apr. 27, 2012) (finding inequitable conduct allegations to be without merit, and noting with respect to deceptive intent that "there was no benefit to [the unnamed inventor] having his name removed as an inventor, and had

he in fact been listed as an inventor, he nevertheless would have been contractually obligated to assign any of his patent rights to [the patent holder]”)). Instead, Auxilium maintains, the only reasonable inference would be that, at the time Gyurik submitted his patent application, he believed “his inventive transdermal testosterone formulations worked for their intended purpose - and that the Conrex in vitro research would not have been material to his claimed invention precisely because it did not work.” Pl. Opp’n, ECF No. 83 at 22.

Furthermore, Auxilium asserts that Watson has failed to identify who should have been named as co-inventor. Auxilium asserts that the Conrex formulations did not work, and therefore there were no other inventors to be named. Id. at 22-23. Additionally, Auxilium contends that even if an individual at Conrex was an inventor, Bentley still owned both inventions of Conrex, by virtue of the Asset Purchase Agreement, and therefore Bentley therefore had nothing to gain from the alleged deception. Id. at 22.

This Court finds that Watson has sufficiently alleged an “intent to deceive.” Watson’s proposed amendment includes the “who, what, when, where, and how of the material misrepresentation or omission committed before the PTO” and “provide[s] particular facts from which a court may reasonably infer that a party acted with the requisite state of mind: (1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) specific intent to deceive the PTO.”⁴ See Exergen Corp., 575 F.3d at 1327; Marlowe Patent

⁴The court in Exergen Corp. denied movant’s motion to amend its pleading because the pleading did not provide any factual basis to infer that any specific individual, who owed a duty to disclose, knew of the specific information that was alleged to be material. Exergen, 575 F.3d at 1329. Furthermore, the pleading failed to identify the “what” and “where” of the material omissions and pled only on belief. Id. at 1329–30. Pleading on belief is permitted under Rule 9(b) when “essential information lies uniquely within another party’s control, but only if the pleading sets forth the specific facts upon which the belief is reasonably based.” Id. at 1330.

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Holdings LLC, 2013 U.S. Dist. LEXIS 26533, at *7; see also Def. Reply Br., ECF No. 87 at 10; Prop. Am. Answer, Affirmative Defenses, ECF No. 81 ¶¶ 26-28, 40. Watson alleges that during the prosecution of the patents-in-suit: (1) Gyurik knew of Conrex’s research concerning pharmaceutical compositions comprising testosterone and oxacyclohexadecan-2-one, and specifically the July 1994 Testosterone Permeation Study, and the September 1994 Testosterone Permeation Study; (2) the information came from Conrex through Bentley’s purchase of Conrex’s research and Gyurik knew that the information was material to the patentability of the patents-in-suit; and (3) Gyurik used the Conrex formulations in his research and actually derived the claimed formulations from the testosterone formulations developed and tested by Conrex.⁵ *Id.* ¶¶ 26-28, 68–69.

While Auxilium argues that Watson must meet a “single most reasonable inference” standard (Pl. Opp’n, ECF No. 83 at 22), Therasense did not address whether intent to deceive must be the single most reasonable inference able to be drawn at the pleading stage because that case was decided on the merits, not the pleadings. See Therasense, 649 F.3d at 1290; Taro Pharm. N. Am.

⁴(...continued)

However, in Exergen Corp., the movant had not provided either the “information” on which it relied or any plausible reasons for its “belief.” *Id.*

⁵ The Court in Sepracor Inc. held that parties alleging inequitable conduct must provide specific names of individuals involved in the alleged inequitable conduct. Sepracor Inc., 2010 U.S. Dist. LEXIS 56221, at *19 (holding that the defendant identifying the “who” as “patent applicants” and “Sepracor” in its Amended Answer when discussing the intent of the alleged misrepresentation was not sufficient to satisfy this element). Similarly, the court in Waddington N. Am., Inc. held defendant’s allegations did not satisfy the pleading standards of Exergen Corp. because the defendant had not identified any specific individuals in connection with the false representations it alleged. Waddington N. Am., Inc., 2010 U.S. Dist. LEXIS 103955, at *17. However, these cases are distinguishable as the proposed Amended Answer clearly identifies Gyurik as the individual who failed to state that Conrex was a co-inventor.

Inc., 2012 U.S. Dist. LEXIS 89702, at *13 (“While Therasense established a more stringent standard for proving inequitable conduct, the decision did not address whether Therasense’s more stringent standards . . . should apply at the pleading stage. It appears that it should not.”).

Lastly, much of Auxilium’s arguments are actually disputes of fact not relevant to the pending motion. For example, Auxilium’s allegation that neither Gyurik nor Bentley had anything to gain from withholding the Conrex in vitro research from the PTO is a matter to be decided at trial. See Twombly, 550 U.S. at 570; Iqbal, 556 U.S. at 678. Whether Watson can prove the allegations proposed in the Amended Answer remain to be seen. But at this stage in the proceedings, the issue is whether Watson has properly pled those allegations. For the reasons set forth above, and without prejudice to the right of Auxilium to move to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) or for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c), the Court concludes that Watson has satisfied Rule 15.

IV. CONCLUSION

For the reasons stated herein, the Court grants Watson’s motion for leave to amend its answer to add its allegations that the patents-in-suit are unenforceable due to inequitable conduct.

s/Michael A. Hammer
UNITED STATES MAGISTRATE JUDGE

Dated: October 2, 2013